



(1) Publication number: 0 439 061 B1

12)

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication of patent specification: 27.07.94 Bulletin 94/30
- (5) Int. Cl.⁵: **A61K 33/14**, A61K 33/10, A61K 33/06
- (21) Application number: 91100527.0
- 2 Date of filing: 17.01.91
- (4) Intravenous solutions for influencing renal function and for maintenance therapy.
- (30) Priority: 19.01.90 US 467166
- (43) Date of publication of application : 31.07.91 Bulletin 91/31
- (45) Publication of the grant of the patent: 27.07.94 Bulletin 94/30
- 84 Designated Contracting States : DE FR GB IT SE
- (5) References cited: EP-A- 437 274 EP-A- 0 076 658 EP-A- 0 177 614 WO-A-87/03808 WO-A-87/03809 DE-A- 2 358 759

- (3) Proprietor: Kopp, Klaus F. Dr. Assikofener Strasse 4 D-85560 Ebersberg (DE)
- (7) Inventor: Kopp, Klaus F. Dr. Assikofener Strasse 4 D-85560 Ebersberg (DE)
- (4) Representative: Müller-Boré & Partner Patentanwälte Postfach 26 02 47 D-80059 München (DE)

439 061 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

EP 0 439 061 B1

pH 7,43, PCO₂ 42 mmHg, HCO-₃ 28 mmol/l, BA + 3,9.

Summary:

High daily urine volumes. Progression without complications. Observation period 2 days. Metabolites concentration, electrolytes and blood gases essentially normal.

Diagnosis:

Stenosis of Urethra, Prostata-Carcinoma, Diab. mellitus

Operation:

Pelvine Lymphadenectomy

2880 ml

Progression: Diuresis:

1st day:

2nd day:

3rd day:

2200 ml 4030 mł

Infusion program:

2000 ml Bicarbonate-electrolyte solution, + 20 mg Lasix + 40 mval KCI 1st day:

1000 ml Glucose 5 %

2nd day:

2000 ml Bicarbonate-electrolyte solution, 40 rnval KCl, 20 mg Lasix

1000 ml Glucose 5 %

3rd day:

2000 ml Bicarbonate-electrolyte solution, + 40 mval KCl, 20 mg Lasix

4th day:

1000 ml Bicarbonate-electrolyte solution, + 40 mval KCI, 20 mg Lasix

Balance:

1st day:

- 470 ml

2nd day:

+ 1490 ml

3rd day:

- 530 ml

Serum values:

1st day:

Urea-N. 21 mg/dl (norm 7-18), Uric acid 8,9 mg/dl (-7)

other values normal

2nd day:

mild higher value of Urea N. and Uric acid Protein 4,9 g/dl (6-8), Ca 7,8 mg/dl (8,7-10,5)

pH 7,41, PCO₂ 49 mmHg, HCO-3 31 mmol/l, BA + 5,4

3rd day:

Chloride 96 mmol/l (97-108), Ca. 7,8 mg/dl, Protein 4,9 g/dl

other values normal

pH 7,49, PCO₂ 48 mmHg, HCO-₃ 37, BA + 12,5

4th day:

Uric acid. 8,9 mg/dl, Potassium 3,4 mmol/i, Ca 8 mg/dl

Phospor 2,3 mg/dl (2,5-4,5), Protein 4,9 g/dl

other values normal

High daily urine volumes. Stabilized metabolites, electrolytes-values, Protein mildly lower. Transferred to General clinic on 4th postoperative day = end of observation. Uncomplicated progression.

The components of the solutions may be provided in combined or separated form. Of course, the solutions of the invention may comprise additional substances, such as pharmaceuticals, trace elements, soluble and stable Ca and/or Mg compounds. For example Ca and/or Mg compounds or components may be provided in a container, such as a flexible bag, separate from the bicarbonate component.

Claims

55

1. Use of an aqueous solution comprising at least the following electrolytes at the concentration indicated below.

EP 0 439 061 B1

mval/l.

Na+	130 to 150 0 to 6 80 to 125	
K+		
CI-		
HCO2-	25 to 70	

in the preparation of an intravenous medication solution in the treatment of patients suffering from renal dysfunction or renal failure to increase urine volume and stabilize acid-base balance.

The use of an aqueous solution according to claim 1, in which the electrolytes are at the concentrations indicated below:

mval/L

20	Na+	135 to 146
	K +	2 to 5
•	a-	90 to 110
		40 to 60
25	HCO ₂ -	70 10 00

The use of an aqueous solution according to claim 2, in which the electrolytes are at the concentrations indicated below:

30		mval/L
	Na ⁺	146
35	K+	4
	a - ·	90
	HCO3	60

- 4. The use of an aqueous solution according to any one of claims 1 to 3, wherein the treatment is followed by a maintenance therapy using an aqueous solution comprising HCO₃⁻ in the range of 25 to < 40 mval/1.</p>
- The use of an aqueous solution according to any one of claims 1 to 4, in which the aqueous solutions are provided in conjunction with a solution of a Ca and/or Mg compound.
 - 6. The use of an aqueous solution according to claim 5, in which the solution of the Ca and/or Mg compound is provided in a container, such as a flexible bag, which is separate from the HCO₃⁻ electrolyte.
- The use of an aqueous olution according to any one of the claims 1 to 6, in which the therapy involves administration of diuretics to increase diuresis.
 - The use of an aqueous solution according to claim 7, in which the therapy involves administration of loop diuretics to increase diuresis.

55

5

10

15